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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,663	02/27/2002	A. K. Gunnar Aberg	559P017	3512
42754	7590	01/19/2006		
NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581				
			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,663	Applicant(s) ABERG ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/04/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-10,13-15,18,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☐ Claim(s) 1,7-10,13-15,18,19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Sept. 22, 2005 and supplemental response of Nov. 4, 2005 have been entered and considered carefully.

Claims 2-5, 11-12, 16-17, 20 have been canceled. Claims 1, 6-10, 13-15, 18-19, and 21 are pending.

2. The rejection of claims 1, 7-10, 13-15, 18-19 and 21 under 35 USC 112 second paragraph is maintained for reason of record.

The ambiguity of the scope of the claims is self-evidenced in view of the specification. Applicants argued that the limitation of the structural formula and the term “being substantially free of the corresponding R-isomer” would be clear is erroneous. Please note that on page 3 of the specification it was clearly disclosed that there are “other metabolites” of ketotifen which are also formed in the body, therefore, if applicants’ claims are drawn to Norketrofen i.e. the R is H compound in its “S” form substantially free from the “R” form, then the claims should be clearly pointing out only the structural formula, irrespective of whether the compound is a metabolite or not, with the required enantiomeric quantity limitation.

3. The rejection of claims 1, 7-10, 13-15, 18-19 under 35 USC 112 first paragraph is maintained for reason of record and is applicable to newly added claim 21.

Please note that to the extend the term “substantially pure” of claim 21 is any form of purity other than one “enantiomeric” form over another enantiomeric form, the claims are considered to contain NEW MATTER. Please note that on page 9 of the specification it was clearly disclosed that an enantiomeric purity was measured. Enantiomeric purity is only measuring quantity of one optical isomer vs quantity of its corresponding optical isomer i.e. an indication of optical separation which is not identical to the “purity” of a product which must be concerned with the content of material “other than” the product. Such content of contamination was neither disclosed nor enumerated to be 95%. Therefore, a claim to such purity is new matter. Removal of all new matter is required. In re Russmussen 211 USPQ 325.

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To the extent that the treatment using the compounds is broadly for “allergic disorders, dermal disorders, bronchial disorders, pulmonary disorders and gastroenterological disorders” are intended for any and all of disorder categorized medically under these conditions, the claims are considered lacking of description and enablement and are NEW MATTER. Please note that for the activity of S-Norketotifen, were the method of use claims are based upon the well known efficacy of ketotifen, then, no evidence or description can be found for such scope of enablement since ketotifen is known for treating conditions such as asthma, COPD.... (see claims 8 and 9). Nowhere in the specification described or enabled the S-Norketotifen has any efficacy in treating all allergic disorders, dermal disorders..... *other than* those known for ketotifen. In addition, the “S” norketotifen is the (-)form of the ring system, such ring system has been known to have “lesser” activity then the (+)form (see CA 112:216595 English abstract of Polivka II). Nowhere in the specification disclosed that the lesser active ring system has “additional” therapeutic activity. Therefore, to the extent that the scope of treating for “allergic disorders, dermal disorders, bronchial disorders, pulmonary disorders and gastroenterological disorders” are intended for any and all of disorder categorized medically under these conditions, it is considered new matter. Removal of all new matter is required.

4. The rejection of claims 1, 7-10, 13-15, 18-19 and 21 under 35 USC 103(a) over Aberg I or II in view of Polivka I or Polivka II is maintained for reason of record.

Applicants argued *vigorously* that no expectation should be given to the demethylated optical isomers (norketotifen) just because the optical forms of methylated isomers (ketotifen) having similar activity. Applicants’ attention is drawn to the references recited on PTO-1449, particularly by Kennedy (research and Clin. Forums, v.4, p.17-20) wherein it was clearly stated “the demethylated product has pharmacological activity similar to ketotifen” (page 17, paragraph describing figure 2). Therefore, such delineation is no the examiner’s imagination but a well-known fact of the prior art.

In addition, the reference by Mey et al. *Drug Metabolism and disposition* (recited on 1449) clearly explained that the alleged “atropisomerism” chirality by applicants is “due to a nonplanar seven-membered ring containing a keto group” (see p.1281 left column), thus, has nothing to do with the methylation or demethylation of the piperidiny ring. Therefore,

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applicants' argument based on the methyl group at no stereo hindered site does not provide any merits for unobviousness.

5. Claim 6 has been allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan 17, 2006


Celia Chang
Primary Examiner
Art Unit 1625